

### **REMARKS**

Applicant respectfully requests reconsideration. Claims 14, 15 and 18-28 were previously pending in this application. No new matter has been added.

### **Rejections Under 35 U.S.C. § 103**

The Examiner rejected the claims under 35 U.S.C. § 103(a) as being unpatentable over Brooke et al. (U.S. Patent 6,328,992) in view of Travis (U.S. Patent 6,541,510) and Turner et al. (J. Clin. Pharmacol. 1981; 21:283S-291S). Applicant respectfully traverses the rejection, and requests reconsideration based on the following remarks as supported by the Declaration of Dr. Brian Whittle, filed herewith.

#### **The cited prior art does not teach all of the elements of the claimed invention**

Applicant submits that the combination of prior art cited by the Examiner does not provide all of the elements of the claimed invention.

According to Dr. Whittle, the Examiner has misconstrued the teachings of the Brooke et al. reference that a person of ordinary skill in the art would understand. Whittle Declaration, ¶ 3. In particular, the Examiner may have reached a conclusion based on an incorrect equivalence of the terms cannabis and cannabinoids, whereas cannabinoids are believed to be only a small proportion of the compounds present in cannabis plant. Whittle Declaration, ¶ 3.

More specifically, Dr. Whittle, the Examiner's statement in the last sentence of the second full paragraph on page 3 of the Office Action is incorrect. The reason that this statement is incorrect is that not all of the individual compounds present in cannabis plant will be active. Whittle Declaration, ¶ 4. In addition, Dr. Whittle states that "any one compound will not be beneficial in treating all of the listed ailments" of Brooke et al. Whittle Declaration, ¶ 4. It is Dr. Whittle's opinion that the person of ordinary skill in the art would most likely attribute the beneficial activities of "cannabis" to either THC and/or CBD. Dr. Whittle states that the

cannabinoid mixture in the Brooke et al. drug formulation includes approximately equal proportions of THC, CBD and CBN, and that *there is no recorded CBC in the Brooke et al. drug formulation*. Whittle Declaration, ¶ 4.

In summary, Dr. Whittle is of the opinion that a person of ordinary skill in the art would not link the two distinct statements of Brooke et al. that “several medicinal uses have been found for the **active ingredients** of cannabis, including the ingredients THC, CBN, CBD and CBC”, and the listing of “the medicinal uses of **cannabis**”. Whittle Declaration, ¶ 11. In Dr. Whittle’s opinion, the skilled person would not have combined these statements as the Examiner did to infer that each listed *active ingredient* may be used to treat any indication, taught for *cannabis*, because the first statement “relates to active ingredients, e.g. pure phyto cannabinoids or synthetic cannabinoids,” while the second statement relates to “uses of cannabis”. Whittle Declaration, ¶ 11.

Dr. Whittle states that treatment of mood disorders are “not suggested in Travis and Turner, which suggest uses for the “active ingredient” cannabichromene.” Whittle Declaration, ¶ 11. Thus the Travis and Turner references do not provide the elements of the claimed invention that are missing from the Brooke et al. reference.

*The prior art does not provide any reason to use cannabichromene for treatment of mood disorders, or a reasonable expectation of success in treating mood disorders*

Regarding the claimed methods for treating a mood disorder in a human patient, Dr. Whittle asserts that a person of ordinary skill in the art would most likely attribute any effect to THC, and “would also be well aware that cannabis is also considered, by many, to be responsible for causing depression”. Whittle Declaration, ¶ 5.

Based on the foregoing, Dr. Whittle concludes that “the ordinary skilled person would NOT have been motivated by the teaching of Brooke et al to use cannabichromene to treat mood disorders. Indeed, it is more likely that reports linking cannabis with mental illness would have led the skilled person in other directions.” Whittle Declaration, ¶ 6. Thus the skilled person

would not have had a reason to make or use the claimed invention. Indeed, the prior art could be viewed as teaching away from the claimed invention because the person of ordinary skill in the art might be prejudiced against using a cannabinoid in the treatment of mood disorders.

Dr. Whittle is of the opinion that the skilled person would not have selected CBC for treating mood disorders “given the link between cannabis and depression, and would not have had a reasonable expectation of success in making or using the claimed invention.” Whittle Declaration, ¶ 11.

*Cannabichromene content of cannabis plants and uses thereof*

In referring to the Vogelmann et al. reference and the Rowan and Fairbairn reference, the Examiner states that: “Applicants contend that one would interpret that the medicinal uses of cannabis [described by Brooke] would not include CBC as a candidate compound to try for any medicinal indication.” Office Action at page 3-4.

Applicant does not agree with the Examiner’s statement, for the reason that various cannabinoids may have a medicinal use. Whittle Declaration, ¶ 7.2. However, Dr. Whittle states that “it is reasonable to conclude that a skilled person would have concentrated on the **primary cannabinoids** THC and CBD and NOT a minor cannabinoid, such as CBC, particularly given that CBC is only found in very small quantities in mature plants and it is use of “cannabis” from these mature flowering plants which provide the anecdotal evidence for many of its medicinal applications”. Whittle Declaration, ¶ 7.2.

Regarding the teachings of the prior art, Dr. Whittle states that both Vogelmann et al., and Rowan and Fairbairn, support the argument that CBC is not found in any significant amount in mature plants. According to Rowan and Fairbairn, there are two basic types of cannabis plants: THC-rich and CBD-rich (fibre type), but there are no predominant CBC types. Whittle Declaration, ¶ 8.

Applicant also disagrees with the Examiner's comments that "Rowan and Fairbairn teach that THC-rich race always possesses CBC sometimes in large amounts", that "Vogelmann et al. teaches that in some light situations there is a higher concentration of CBC compared to THC and CBG", and that "accordingly, there is no reason to expect that CBC would not have any medicinal purpose." Office Action at page 4.

In particular, Dr. Whittle states that "Vogelmann makes it quite clear that, in the flowering plant, (and the cannabinoids predominate in the head) CBC is found in **relatively small** amounts (Table 1)". Whittle Declaration, ¶ 9. According to Dr. Whittle, the skilled person would think that the effect of mature cannabis plants would be attributable to "one or more of the predominant constituents, rather than relatively minor constituents" such as cannabichromene. Whittle Declaration, ¶ 9.

Moreover, the information cited by the Examiner appears to be out of the context in which it was presented by the prior art. Whittle Declaration, ¶ 9. For example, the teaching of higher CBC levels by Vogelmann et al. relates to "non-mature plant material" and consequently the statement, and its relevance to "cannabis" (as it is used medicinally/ recreationally) is misleading." Whittle Declaration, ¶ 9.

The same is true of the teaching of CBC levels plants by Rowan and Fairbairn, which "make it quite clear that their work is conducted on 14 day old material." Whittle Declaration, ¶ 10. Again, the Examiner quotes material from the prior art out of its original context, which refers to seedling material, but not mature cannabis plants. Whittle Declaration, ¶ 9. As noted by Dr. Whittle, reference to Table 2 of Rowan and Fairbairn shows that the combined CBC and CBD (not an ideal comparison) content in 14 day old seedlings and mature plants is radically different. Whittle Declaration, ¶ 10.

Thus, in Dr. Whittle's opinion, the skilled person would have focused attention "on the major cannabinoids THC and CBD and would have been **dissuaded from looking at CBC** because it is a cannabinoid that does **NOT** generally prevail in **mature plants**, and it is the

anecdotal uses of such **mature cannabis plants** which provides the necessary motivation.”

Whittle Declaration, ¶ 11.

Summary

In view of the foregoing remarks, Applicant submits that the Examiner has not made a *prima facie* case of obviousness, because (1) the combination of cited prior art does not provide all of the elements of the claimed invention, (2) there is no valid reason to combine the references, and (3) the skilled person would not have a reasonable expectation of success in making or using the claimed invention based on the combined teaching of the prior art.

Accordingly, Applicant respectfully requests withdrawal of the rejection of claims 14-15 and 18-28 under 35 U.S.C. § 103.

**CONCLUSION**

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,  
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Docket No.: B0192.70062US00  
Date: December 1, 2008  
**X11/30/08x**